

## REMARKS

### ***Remaining Claims***

Eight (8) claims (Claims 1 - 3 and 5 - 9) remain pending in this application through this Amendment. Claims 4 and 10 - 14 have been cancelled. Claims 1 and 2 have been amended by this amendment.

### **Rejections under 35 U.S.C. §112, first paragraph**

Claim 1 has been amended as suggested by the Examiner to overcome the §112, first paragraph rejection. Applicants wish to express their appreciation to the Examiner for his kind suggestion in this regard.

### **Rejections under 35 U.S.C. §112, second paragraph**

Claims 1-3 and 5-9 were rejected under 35 U.S.C. §112, second paragraph, because "hydrophilic" in Claim 1 is indefinite. For the following reasons, the Examiner's rejection over claims 1-3 and 5-9 is respectfully traversed.

First, Applicants respectfully submit that the term "hydrophilic monomer" has been extensively used by the biomedical device industry, in particular by contact lens industry, to make a hydrogel material. For example, By performing, on May 5, 2004, a simple patent search in the U.S. PTO patent database based on the terms "**hydrophilic monomer**" AND "**contact lens**", Applicants have found 428 US patents which are issued since 1976 and each contain the term "hydrophilic monomer". This clearly indicate that one of ordinary skilled in the art would understood the metes and bounds of the definition of the term "hydrophilic monomer". Furthermore, the definition for "hydrophilic monomer" provided by some patents is consistent with the definition provided by Applicants in the specification. For example, U.S. Patent No. 5,292,350, in col. 4, lines 22-34, states that

As used herein, a soft hydrogel contact lens refers to a gel- like lens derived from a hydrophilic polymer composition which is swollen with a significant amount of water, typically greater than 30 percent and preferably at least 65 percent. **A hydrophilic monomer refers to any monomer which, when polymerized, yields a hydrophilic polymer capable of forming a hydrogel when contacted with water.** Examples of hydrophilic monomers include hydroxy esters of acrylic or methacrylic acid, N,N dimethylacryamide, (DMA), N-vinyl pyrrolidone (NVP), and styrene sulfonic acid, or other hydrophilic monomers known in the art. [Emphasis added]

U.S. Patent No. 5,311,223, in col. 3, lines 54-63, states that

For the purpose of defining this invention, **a "hydrophilic monomer" refers to any monomer or mixture of monomers which, when polymerized, yields a hydrophilic polymer capable of forming a hydrogel when contacted with water.** Examples of hydrophilic monomers include, but are not limited to, hydroxyesters of acrylic or methacrylic acid, methacrylic acid (MAA), hydroxyethyl methacrylamide (HMA), DMA, NVP, styrene sulphonic acid, and other hydrophilic monomers known in the art. [Emphasis added]

Second, when defining a monomer or any material with the term "hydrophilic", the term "hydrophilic" is ***only*** relative to "hydrophobic". Webster's NEW World™ College Dictionary gives

"hydrophilic", "hydrophobic" and "monomer" the following definitions: "**hydrophilic**" as "capable of uniting with or taking up water", "**hydrophobic**" as "not capable of uniting with or taking up water", and "monomer" as "a simple molecule that can form polymers by combining with identical or similar molecules". There is clear cut between "hydrophilic" and "hydrophobic". Even just by relying on Webster's NEW World™ College Dictionary, one can clearly understand the meets and bounds of the definition of the term "hydrophilic monomer".

Applicants respectfully disagree with the examiner about the statement that "one of ordinary skill in the art would not know what percent solubility is necessary, or under what conditions solubility or water uptake is to be measured. Applicants believe that there is not need to specify a percent solubility when talking about "water soluble". In fact, it is widely accepted in chemistry that "water soluble" can be used to describe a material. For example, CRC Handbook of Chemistry and Physics 81<sup>st</sup> Edition uses this term "water-soluble" in Solubility Chart (from page 8-116 to 8-118, see the attachment), even without specifying under what conditions (e.g., temperature) is measured. It is generally a common notion that the solubility of a material is measured at room temperature. Applicants also submit that measurements of a percentage by weight of water absorbed by a polymer (e.g., hydrogel) is a well established standard procedure, in particularly in contact lens industry as confirmed by ISO 10339 and ANSI Z80.20-1998 (page 59) submitted herewith. Both documents clearly confirm that there is a well-established standard for determination of water content/absorption and that a person skilled in the art should know well how to determine is water content/absorption by a hydrogel material under which conditions.

In sum, the language of Claim 1 is definite because "hydrophilic" is a term the meets and bounds of which can be determined by a person skilled in the art. Applicants respectfully request withdrawal of rejection under 35 U.S.C. §112, second paragraph, of claim 1 and its dependent claims 2-3 and 5-9.

Claim 2 has been amended in accordance with Examiner's suggestions to use proper Markush language and to make the nesting of groups clear by the use of indentation and/or punctuation.

### **CONCLUSION**

In view of the foregoing and in conclusion, Applicants submit that the rejections set-forth in the Office Action have been overcome, and that all pending claims are now in condition for allowance.

Should the Examiner believe that a discussion with Applicants' representative would further the prosecution of this application, the Examiner is respectfully invited to contact the undersigned. Please address all correspondence to Robert Gorman, CIBA Vision, Patent Department, 11460 Johns Creek Parkway, Duluth, GA 30097. The Commissioner is hereby authorized to charge any other fees which may be required under 37 C.F.R. §§1.16 and 1.17, or credit any overpayment, to Deposit Account No. 50-2965.

Respectfully submitted,



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